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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/736,619	12/13/2000	Igor Markidan	4389-9	8901

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EXAMINER

HARLE, JENNIFER I

ART UNIT	PAPER NUMBER
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3627

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/736,619

Applicant(s)

MARKIDAN ET AL.

Examiner

Jennifer I. Harle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-9 are pending. Claims 1-9 are rejected.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case, claims 1-3 and 5 only recites an abstract idea. The recited steps of merely tracking samples of a clinical study by defining clinical study protocols comprising a plurality of procedures including accessioning samples by recording them in a database, creating worklists by assigning scientists to perform procedures, creating checklists, performing steps on the checklist and recording completion of steps on the checklist in the database does not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in

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the mind of the user or by use of a pencil and paper. The samples could be the people themselves and the procedures could involve psychiatric, physical or speech evaluation. A database can be a paper file, notecards, etc. These steps only constitute an idea of how to track samples of a clinical study.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the tracks samples of a clinical study by defining the protocol, accessioning samples creating worklists and checklists, performing steps on the checklists and recording the results of the steps performed (i.e., repeatable useful and tangible).

Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claims 1-3 and 5 is deemed to be directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-6, and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Oku, et al. (5,675,745).

Oku teaches all the claim elements as set forth by Applicants in claims 1-3, 5-6, and 8. See entire patent but specifically Figs. 1, 3, 6, 8, 10, 12-13, 16-19, 21-26, 30-31, 33-35, 41-42,

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44-52, 54, 58-60; cols. 1-2, lines 10-14, cols. 5-6, lines 21-25, col. 9, lines 20-24, col. 10, lines 8-42, cols. 12-13, lines 49-41, col. 20-23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 7, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oku, et al. (5,675,745) in view of William E. Evans and Mary V. Relling, Pharmacogenomics: Translating Functional Genomics into Rational Therapeutics, Science, Vol. 286, Issue 5439, October 15, 1999, pp. 487-491.

Oku teaches as set forth above. However, Oku does not teach that one of the procedures determines the genotype of an individual. Evans teaches determining the genotype of an individual in conjunction with clinical studies. Evans further teaches that determining an individual's genotype is associated with disease risk and drug toxicity, is likely to constitute part of the mechanism for so-called "idiosyncratic drug reactions, drug-metabolism genotypes may result in a phenotype in the absence of drug, and that common polymorphisms in drug targets dictate that DNA sequence variations be taken into account in the genomic screening processes aimed at new drug development to provide new insights for the development of medications that target critical pathways in disease pathogenesis and medications that can be used to prevent diseases in individuals who are genetically predisposed to them. (Pp. 1-4 of 8 and Fig. 3) Evans thus teaches that automated systems are being developed to determine an individual's genotype

for polymorphic genes that are known to be involved in the pathogenesis of their, disease, in the metabolism and disposition of medications, and in the targets of drug therapy, which need be performed only once for each battery of genes tested and can then become the blueprint for individualizing drug therapy. (Pg. 6 of 8 and Fig. 3) Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included determining an individuals genotype as taught by Evans into the system and method of Oku for the specific reasons set forth in Evans.

Conclusion

In accordance with the USPTO's goals of customer service, compact prosecution, and reduction of cycle time, and because "the continual, chief complaint of inventors and their lawyers: that patent examiners are abysmal communicators, both orally and in writing,"¹ the Examiner has made every effort to clarify his position regarding claim interpretation and any rejections or objections in this application. Furthermore, the Examiner has provided Applicant(s) with notice—for due process purposes—of his position regarding his factual determinations and legal conclusions. If Applicant(s) disagree with *any* factual determination or legal conclusion made by the Examiner in this Office Action whether expressly stated or implied,² the Examiner respectfully requests Applicant(s) *in their next response* to expressly traverse the Examiner's position and provide appropriate arguments in support thereof. Failure by Applicant(s) *in their next response* to traverse the Examiner's positions and provide appropriate arguments in support thereof will be considered an admission by Applicant(s) of

¹ Sabra Chartrand, *A Bid to Overcome Patent Backlogs*, 152 N.Y. Times C2 (Sept. 23, 2002).

² E.g., if the Examiner rejected a claim under §103 with two references, although not directly stated, it is the Examiner's implied position that the references are analogous art.

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the factual determinations and legal conclusion not expressly traversed.³ By addressing these issues now, matters where the Examiner and Applicant(s) agree can be eliminated allowing the Examiner and Applicant(s) to focus on areas of disagreement (if any) with the goal towards allowance in the shortest possible time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (703) 306-2906. The examiner can normally be reached on Monday - Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert P. Olszewski can be reached on (703) 308-5183. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7687 for regular communications and (703) 305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

Jennifer Ione Harle
June 16, 2003


Richard Chilcot
~~Supervisory Patent Examiner~~
Technology Center
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³ See also MPEP §714.02, 37 CFR §1.111(b), and 37 CFR §1.104(c)(3).